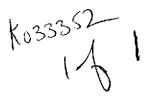
VERTEBRON, INC. 510(k) NOTIFICATION



510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER

Vertebron, Ltd.

Stratford, CT 06614

CONTACT PERSON

Bruce Khalili

Vice President, Research & Development

DATE PREPARED

October 15, 2003

CLASSIFICATION

Spinal Intervertebral Body Fixation Orthosis

Spinal Interlaminal Fixation Orthosis

Spondylolithesis Spinal Fixation Device System

Pedicle Screw Spinal System

COMMON NAME

Spinal Rod System

PROPRIETARY NAME

Vertebron PSS™ Pedicle Screw System

PREDICATE DEVICES

U.S. Surgical/S.D.I. K970635 (et al)

Depuy/Acromed K030383 (et al) Sofmor/Danek K022778 (et al)

DEVICE

DESCRIPTION

The device consists of a system of implantable rods, screws and hooks for the purpose of aiding in spinal fusion. The

system also includes various hand tool used to assist in implantation of the rod system. Implantable components are composed of titanium alloy meeting the requirements of ASTM F136-98. The device is supplied non-sterile and is

intended for sterilization by hospital personnel.

TESTING

The device has been tested in accordance with the

requirements prescribed in ASTM F1717. The device was found to perform comparably to other spinal rod systems.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

FEB 2 5 2004

Mr. Bruce Khalili Vice President, Research and Development Vertebron, Inc. 136 Albert Avenue Stratford, Connecticut 06614

Re: K033352

Trade/Device Name: VERTEBRON[™] PSS Pedicle Screw System

Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070

Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system

Regulatory Class: II

Product Code: MNI, MNII, KWQ, KWP

Dated: January 16, 2004 Received: January 20, 2004

Dear Mr. Khalili:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Bruce Khalili

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

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Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

for Med M. Muller (Division Sign-Off)

Division of General, Restorative, and Neurological Levices

510(k) Number <u>K03335</u>

Indications for Use

510(k) Number (if known): K033352

Device Name: VERTEBRON PSS Pedicle Screw System

Indications For Use:

The Vertebron PSS Pedicle Screw System is intended for non pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The Vertebron PSS Pedicle Screw System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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